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October 11, 2005

The Honorable Kent A. Jordan
United States District Judge
J. Caleb Boggs Federal Building
844 North King Street, Room 6325
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. Razadyne® Litigation: Civil Action Nos. 05-356-KAJ, 05-371-KAJ, 05-380-KAJ, 05-381-KAJ, 05-382-KAJ, 05-420-KAJ, and 05-451-KAJ

Dear Judge Jordan:

I am writing in advance of the Rule 16 conference scheduled for 9:00 a.m. tomorrow in the above seven cases to provide a brief explanation of plaintiffs' positions on the disputed points in the joint proposed scheduling order submitted to the Court on October 6, 2005. Although plaintiffs recognize that the Court has not requested such a submission, it was our hope that given the sheer number of parties and cases, Your Honor would find it helpful to receive some advance explanation of our point of view rather than hear it for the first time upon taking the bench tomorrow morning.

These seven actions involve essentially the same operative facts, claims and defenses. Plaintiffs are the owner and licensee of a patent (the '318 patent) claiming the use of the chemical compound galantamine hydrobromide for the treatment of Alzheimer's disease. Galantamine hydrobromide is the active ingredient in Janssen's Razadyne® drug product, which is approved for the treatment of Alzheimer's. Defendants in the seven cases are generic pharmaceutical firms (or their parent corporations) that each filed an Amended New Drug Application ("ANDA") with FDA in April or May, 2005, to market generic versions of Razadyne®.

The principal defense asserted by each defendant is the same – namely, the alleged invalidity of the '318 patent.[1] Accordingly, although each defendant also alleges that it does not infringe the patent, plaintiffs anticipate that the main issue in each case will be the same issue of the validity *vel non* of the '318 patent.

[1] By statute, each generic manufacturer filing an ANDA must provide to the brand name manufacturer and the patent owner a detailed statement, the so-called paragraph IV notice, of the generic manufacturer's allegations as to why the patent(s) covering the brand name drug are invalid or not infringed. *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II).

Consolidation

Plaintiffs propose that these seven cases be consolidated, and we are prepared to move formally for consolidation of the actions if needed. However, we believe that a formal motion may not be necessary, as defendants may well decide to stipulate to consolidation. These cases all involve the same patent, the same alleged infringing actions, and will involve mainly common issues of law and fact. Pursuant to Federal Rule 42(a), these cases should be consolidated in order to avoid unnecessary costs or delay, and in the interest of judicial economy. *See, e.g., Hooker Chem. & Plastics Corp. v. Diamond Shamrock Corp.*, 96 F.R.D. 46, 49 (W.D.N.Y. 1982) (consolidating patent infringement actions on such grounds). *See also United Mine Workers of America v. Gibbs,* 383 U.S. 715, 724, 86 S. Ct. 1130, 1138 (1066) ("Under the Rules, the impulse is toward entertaining the broadest possible scope of action consistent with fairness to the parties; joinder of claims, parties and remedies is strongly encouraged."). In any event, where reference is made herein to each "side," we refer to the defendants from all seven cases collectively as one side, and to plaintiffs collectively as the other.

Overall Schedule

Plaintiffs believe that discovery and pretrial motions in these cases will take approximately 24 months to complete. Defendants assert that 17 months will suffice for fact and expert discovery and pretrial motions.

Plaintiffs' proposed schedule is based on several factors.

- Plaintiffs seek to set a realistic, attainable schedule at the outset, thereby avoiding the need for later requests to the Court for extensions of time.

- There are seven actions pending, and although they are similar in many fundamental ways, the defendant-specific discovery will impose a substantial and unequal fact and expert discovery burden on plaintiffs.

- As to fact discovery, plaintiffs bear the burden of providing fact discovery as to each of the seven defendants, and hence will need to conduct infringement discovery as to each one, as well as discovery as to the facts and contentions of each defendant concerning its allegations of invalidity.

- Plaintiffs anticipate that some foreign country discovery – always a lengthy process – will be necessary in these cases. Plaintiffs' proposed schedule accounts for the fact that some of the anticipated foreign discovery requests cannot properly be made until after plaintiffs have had the benefit of some basic discovery from defendants. Plaintiffs will not be able to make multiple requests for discovery from any foreign entity, and are thus effectively required to wait to issue foreign discovery requests until we can make those requests with proper specificity and completeness.

- As to expert discovery, the salient fact is that defendants have refused to commit to use of any common experts. From a scheduling standpoint, Plaintiffs therefore must allocate sufficient time to allow for the possibility that they may be faced with as many as seven separate expert reports on each scientific or technical issue and with the need to take depositions of a large number of expert witnesses.

For these reasons, plaintiffs believe that the overall schedule proposed by them is more realistic than that proposed by defendants.

Joinder of Other Parties and Amendment of Pleadings (para. 2)

Plaintiffs propose that other parties be joined, and that pleadings be amended or supplemented, no later than 6 months prior to the close of fact discovery. Defendants' proposal provides only 30 days. Thirty days is simply too short to permit adequate discovery of newly added parties or claims, particularly where seven defendant groups are involved. Given that final discovery requests must also be served at least 30 days in advance of the discovery cutoff to provide time for completion, defendants' proposal provides no time at all between receipt at the deadline of new pleadings and drafting and service of discovery regarding those new pleadings.

Bifurcation of Discovery and Trial on Willfulness (para. 3)

Plaintiffs do not believe that bifurcation of discovery or trial on willfulness is appropriate in these cases. "Bifurcation in patent cases, as in others, is the exception, not the rule," *Real v. Bunn-O-Matic Corp.*, 195 F.R.D. 618, 620 (N.D. Ill. 2000), and the party seeking bifurcation has the burden of proving that it is justified. *Belmont Textile Machinery Co. v. Superba, S.A.*, 48 F. Supp. 2d 521, 526 (W.D.N.C. 1999). For the probable adverse effects of bifurcation to be overcome – e.g., additional discovery, more pretrial disputes and motion practice, deposing twice or recalling some of the same witnesses, and potentially engendering more trial and post-trial motions and appeals – "the circumstances justifying bifurcation should be particularly compelling and [should] prevail only in exceptional cases." *Kos Pharm., Inc. v. Barr Labs., Inc.*, 218 F.R.D. 387, 390-91 (S.D.N.Y. 2003); *see also Bunn-O-Matic Corp.*, 195 F.R.D. at 620 ("[t]he piecemeal trial of separate issues in a single lawsuit is not to be the usual course"); *Keyes Fibre Co. v. Packaging Corp. of America*, 763 F. Supp. 374 (N.D. Ill. 1991) (bifurcation rejected as needlessly duplicative because of overlap in evidence, simplicity of damages issues, and lack of prejudice to defendants). "[D]ividing the ultimate resolution of a dispute into separate trials equates to a formula that inevitably works against some or all of the very values of convenience, expedition, economy and avoidance of prejudice that Rule 42(b) prescribes as grounds to warrant bifurcation." *Kos Pharm., Inc.*, 218 F.R.D. at 390.

Bifurcation of these cases would be highly inefficient, requiring two (if not multiple) trials and two separate periods of discovery. Additionally, in Hatch-Waxman cases, which involve bench trials, any argument that defendants would be required to waive attorney-client privilege if discovery or trial is not bifurcated is diminished. *See, e.g., Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99, 101 (N.D. Cal. 1992) (finding attorney-client privilege waiver concerns to be potentially unfounded in light of the fact that trial would be a bench trial);

see also Johns Hopkins Univ. v. CellPro, 160 F.R.D. 30 (D. Del. 1995) ("[s]taying discovery on the advice of counsel defense and ordering a separate trial on willfulness or damages . . . until after liability has been established builds difficult delays and complications into the case"). Finally, unlike in many patent cases, here there are no complex damages issues to be resolved, and thus that potential reason for bifurcation does not exist. *See, e.g., Kos Pharm., Inc.*, 218 F.R.D. at 390 (ruling against bifurcation in ANDA litigation wherein there were no damages issues implicated because defendant's accused infringing product had not yet reached the market).[2] Simply put, there is no compelling justification for bifurcation of liability and willfulness in these cases.

Discovery (para. 4)

The parties have been unable to reach agreement on several substantive provisions regulating discovery, including the hours and locations for fact depositions (paras. 4(a) and (b)), the number of interrogatories (para. 4(c)), and time frames for expert discovery (para. 4(e)).

Given the large number of defendants, plaintiffs seek a total of 250 hours for fact depositions. This is equivalent to only about five 7-hour depositions of each of the seven defendants. Plaintiffs here bear the burden of proving infringement against all of the defendants and consequently need to undertake independent discovery against each one. Hence, in contrast to the defendants' need for common discovery from plaintiffs, plaintiffs need individual discovery from each defendant. Defendants' proposal of a total of 140 hours unfairly limits plaintiffs' opportunity to undertake such individualized discovery.

Although the parties agree that most depositions should be limited to the 7 hour limit specified in the rules, the parties disagree on the number of depositions that should be permitted to exceed this limit, and by how much (para. 4(a)). Defendants assert that they will need to depose the '318 patent's inventor, Dr. Bonnie Davis, for up to 21 hours, and that two additional depositions should be permitted to run up to 14 hours. Plaintiffs believe that a 14-hour deposition of the inventor is sufficient. With adequate preparation and some minimal coordination by defense counsel, plaintiffs believe that the other depositions can effectively be conducted within the 7-hour limit.

Regarding the location of depositions, plaintiffs propose that the party who controls a witness should bring that witness to their local or non-local counsel's office for deposition (para. 4(b)). Defendants' proposal requires the production of parties and their representatives in Delaware. Our more flexible proposal should result in decreased costs.

Plaintiffs propose that interrogatories be limited to 50 per side (para. 4(c)). Plaintiffs believe this is a fair compromise between individual parties' needs to pursue their own discovery

[2] As the *Kos* court aptly noted: "[M]ost of the cases in which bifurcation of the willfulness issue has been found warranted have also entailed claims of damages and a finding by the court of a factual overlap between issues regarding willfulness and those pertaining to damages, which provided a distinct ground supporting a separate trial." *Kos Pharm., Inc.*, 218 F.R.D. at 392.

strategies, and the goal of efficiency given the fundamental similarity of these actions – including that the primary defense asserted by each defendant is the same, invalidity. Defendants' proposal, on the other hand, would permit service of 175 interrogatories by defendants collectively – an excessive number given the similarity of the claims and defenses in each case – while limiting plaintiffs interrogatories to the seven defendant groups to 50 total. Plaintiffs' proposed limit on interrogatories merely requires defendants in these similar cases to coordinate amongst themselves to avoid duplication of requests.

Disclosure of Expert Discovery (para. 4(e))

The principal difference between the parties' expert discovery provisions is the length of time needed for the exchange of expert reports and the taking of expert discovery: plaintiffs believe that 135 days is required; defendants contend that 90 days will suffice.

Of significance, defendants have not been willing to agree to coordinate any of their experts, raising the risk that plaintiffs will need to respond to as many as seven defense expert reports on each of the several scientific or technical issues, and that there will be a great number of expert depositions to be taken in these cases. In light of that possibility, defendants' timetable is unrealistic. If defendants' timetable for expert discovery is adopted, one of two things will result: defendants will be encouraged not to coordinate their use of experts because of the plaintiffs' difficulty in conducting adequate discovery in such a short period of time; and/or one or more parties will have to seek an extension of expert discovery deadlines (and, therefore, all pretrial deadlines and the trial itself).

Tutorial Describing the Technology and Matters in Issue (para. 10)

Plaintiffs believe that the Court will benefit from receiving a tutorial on the relevant technology and issues as early in the case as possible, and propose submitting it to the Court on May 1, 2006, or three months before the defendants propose doing so.

Claim Construction and Briefs (para. 12)

Defendants are seeking the construction of certain patent claims prior to the conduct of expert discovery (paras. 12, 13). Despite plaintiffs' repeated requests, defendants have refused to identify what claim terms they believe will require construction in advance of expert discovery, and why. Plaintiffs believe that any necessary claim construction is properly done at the close of expert discovery in conjunction with dispositive motions – as provided for in the Court's standard scheduling order and in plaintiffs' proposal.

Motions in Limine (para. 17)

Despite the similarity of claims and defenses in these cases, defendants seek to be permitted five motions *in limine* per party. Even if all related defendants were considered a single party for purposes of this provision (which defendants' proposal does not provide), defendants' proposal would result in as many as 35 motions *in limine* filed by the defense side.

Plaintiffs' proposal, that each side be permitted ten *in limine* requests, is far more reasonable for both the parties and the Court, and will afford defendants ample opportunity to raise their pretrial arguments. Plaintiffs' proposal also adopts the Court's standard scheduling order provision requiring that where more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined into a single submission of five pages. Defendants' failure to include the Court's standard provision on this topic means that the seven defendants could choose to file more than one motion on an issue of importance to them and thereby obtain an expanded number of pages for briefing that issue, while still limiting plaintiffs to a five page response. Plaintiffs believe that permitting the seven sets of defendants to file five motions *in limine* each, and to avoid the page limitation governing motions *in limine* on common issues, will prove unfair and vexatious.

We look forward to meeting with Your Honor at the conference tomorrow morning, when we can answer any questions the Court may have regarding plaintiffs' positions on these or other issues.

Respectfully,

/s/ Steven J. Balick

Steven J. Balick

SJB/dmf
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